K113705

AUG 31 2012

Section III

Premarket Notification (510 (k)) Summary

(Per 21 CFR 807.92)

Date:	March 14, 2012
Submitted by:	Pintler Medical 3220 South Hanford Street Seattle, WA. 98144 (206 660 9020)
Contact Person:	Maribeth MacIntyre-Ellis President Phone: 206 660 9020 maribeth@Pintlermedical.com

Device Name

Trade Name:	Pintler Patient Warmer System
Common Name:	Thermal Maintenance System
Classification Name:	Thermal Regulating System
Product Code & Reg. No.	DWJ, 21 CFR870.5900

Substantially Equivalent: The Pintler Patient Warming System is substantially equivalent to the following devices:

PRN ThermalCare 3000 Control Unit and Power Also known as PerfecTemp K062794

Description of the Device: The Pintler Patient Warming System a thermal regulating operating room pad, and a power control unit mounted to a standard IV pole. The operating room pad utilizes a low voltage resistant heating element , DC power and warms patients with conductive warming technology.

Indication for use: The Pintler Patient Warming System aids in the function of assisting in maintaining patient warming during perioperative experience for pediatric and adult patients and would be indicated for use in any condition where patient warming is desired as determined by clinical personnel, in accordance with facility normo-thermia protocol.

Contraindications: Place the unit OFF in all procedures where hypothermic treatment or administration is prescribed or facility procedure. Patient care procedures prescribing hypothermic treatment can or may exhibit an adverse event, i. e. skin damage, skin tissue burns or other types of skin tissue damage from heat.

Patient Population: Pediatric (5 kilo) and Adult (capability of the table to bear weight)

Environment of Use: Hospitals, surgery center and/or other sites designated for surgical procedures

Comparison of Predicated Devices:
The differences between the Pintler Patient Warmer and the predicated device is minimal. Both devices are conductive warmers. Both devices use a resistant warming technology. Both devices require a IV mounted or separate power device for power input. Both devices use a microprocessor for operational functionality and safety. Both devices are required to be compliant to EN60601-1-2.

Testing Safety and Effectiveness: Bench testing for safety of the Pintler Patient Warming System has been completed. Testing was conducted, demonstrated the device met the performance/effectiveness/safety parameters.

Conclusion: Testing and comparison of the Pintler Patient Warming System found the product to be substantially equivalent to the predicated device and there are no new safety or effectiveness issues introduced.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 31 2012

Pintler Medical
c/o Ms. Paula Wilkerson
Senior Staff Engineer, Senior Reviewer
Intertek Testing Services
2307 East Aurora Road, Unit B7
Twinsburg, OH 44087

Re: K113705
Pintler Patient Warming System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: August 22, 2012
Received: August 23, 2012

Dear Ms. Wilkerson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. S. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section II

Statement: Indication for Use

510 (k) Number K113705

Device Name: Pintler Patient Warming System

Patient Population: Pediatric to Adult

Environment of use: Hospitals, Surgery Centers, and other surgical sites

Indication of Use: The Pintler Patient Warming System aids in the function of assisting in maintaining patient warming during perioperative experience for pediatric and adult patients and would be indicated for use in any condition where patient warming is desired as determined by clinical personnel, in accordance with facility normo-thermia protocol.

Prescription Use _X_ Over the counter use_____
Part 21 CFR 801 Subpart D and /or 21CFR 801 Subpart C

(PLEASE SO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGES IF NEEDED)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113705